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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
MANSCHEL, A.	
ART UNIT	**PAPER NUMBER**
1631	14

DATE MAILED: 02/[illegible]/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/344,526	Chee et al.
Examiner	**Group Art Unit**
Ardin Marschel	1631

[X] Responsive to communication(s) filed on *Dec 12, 2000*

[ ] This action is **FINAL.**

[ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

[X] Claim(s) *8-14 and 16-34* is/are pending in the applicat

[redacted], Claim(s) *1-7 and 15 have been canceled.* [redacted]

[ ] Claim(s) _____ is/are allowed.

[X] Claim(s) *8-14, 16-18, and 21-34* is/are rejected.

[X] Claim(s) *19 and 20* is/are objected to.

[ ] Claims _____ are subject to restriction or election requirement.

Application Papers

[ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [X] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____ .

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

[ ] Notice of References Cited, PTO-892

[X] Information Disclosure Statement(s), PTO-1449, [redacted] *(5 sheets)*

[ ] Interview Summary, PTO-413

[ ] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' arguments, filed 12/12/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 8-14 and 21-34 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite as to what is meant regarding the metes and bounds of the phrase "randomly distributed" as given, for example, in claim 8, line 6. It is noted that the substrate is patterned with discrete sites and that microspheres comprising subpopulations are randomly distributed on the surface of the substrate. Such a random distribution may be reasonably interpreted in at least two confusing ways. In one way the entirety of the overall population of microspheres is randomly distributed over the discrete sites on the surface. Another interpretation is that the each subpopulation may be randomly distributed on some part of the surface but not randomly over the entire surface. For example, if one were to place each entire subpopulation of microspheres in each well on the surface of a substrate each

subpopulation would be expected to become randomly distributed within each well. The wells may be patterned as in a microtitre plate on the plastic plate's surface. Thus, a patterned substrate would contain randomly distributed microspheres on the surface. It is acknowledged that applicants may have wished to claim that the random distribution of microspheres be randomly distributed amongst, between, or over the "discrete sites" of the patterned surface rather than randomly distributed only over the smaller surface area within each of the discrete sites, however, the claims do not clearly limit the random practice in this way and leave open the above alternative interpretation. It is noted also that the claims do not require that the microspheres within each subpopulation are distributed over the multiple discrete sites. This unclarity exists in independent claims 8, 13, and 14 and claims dependent therefrom directly or indirectly due to their dependence. Clarification via clearer claim wording is requested. It is suggested that removing this unclarity would be possible by more clearly wording the random practice in the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or

on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 16-18 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Ekins et al.(P/N 5,516,635).

Ekins et al. in Example 5 in column 13 discloses the aliquoting of labeled microspheres in wells of a microtitre plate followed by shaking (a form of agitation) for 0.5 to 1 hour. The wells were washed and scanned for signal which clearly indicates that the labeled microspheres remained in the wells thus documenting that an array of wells containing microsphere particles had been made thus anticipating instant claims 16-18.

Claims 8-18 and 21-34 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Walt et al.(P/N 6,023,540).

Walt et al. discloses the preparation and use of fiber optic sensors with encoded microspheres attached onto the fiber surface in a pattern of discrete sites where the fiber surface contains said microspheres in a random distribution of subpopulations of microspheres as summarized in column 11, line 26, through column 15, line 36. The optical fiber is prepared as described in column 12, lines 16-48, to result in a pattern of discrete sites. Microspheres are then added with various subpopulations of such

microspheres as disclosed in column 12, line 49, through column 13, line 45. The process is outlined in Figure 6. These microsphere subpopulations are decoded via analysis of decoding reagents as described in column 12, line 47, through column 15, line 16. The random distribution of the microspheres requires this decoding in order to define the location of each microsphere for each subpopulation. Figures 8A through 10B illustrate the different microsphere analysis results showing in particular the random distribution of microspheres in discrete sites on the fiber optic sensor. Optical decoding signals are summarized for one case in column 14, lines 52-56. These fiber optic sensors analyze the content of a sample regarding various analytes. The SUMMARY OF THE INVENTION section of the reference illustrates the benefit of the decoding as placing the burden on analysis rather than manufacture as summarized in column 4, lines 15-20. Analytes such as proteins (enzymes - column 8, line 10) or nucleic acid (column 10, lines 4-17, and Table V) may be detected and analyzed via the sensors disclosed in the reference. These disclosures anticipate the above listed instant claims.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 8-14, 21, and 23-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekins et al.(P/N 5,516,635).

Ekins et al. describes the placement of tagged microspheres into microtitre plate wells with which multiple binding assays may be performed (See column 3, line 58, through column 5, line 40, and column 7, lines 57-64.). These microspheres contain bioactive agents such as DNA (column 8, line 39, to column 9, line 22) and protein (column 4, lines 4-9). Identifier binding ligands decode the bound ligands and identify the bound bioactive agent. See column 4, lines 10-62. Bioactive agents with non-optical signatures such as enzymes are described in column 4, lines 10-12. Different subpopulations of microspheres are used

to determine different analytes with different bioactive agents as described in column 5, lines 28-39. Various fluorescent labels for identification are described in column 4, lines 21-39. In the example 5 in the reference in column 13, microtitre plate wells were each aliquoted with fluorescent microspheres solutions of 0.1 μm in diameter in diameter and shaken which clearly would result in a reasonable expectation of success that random distribution of these microspheres occurred within each well. See the above interpretation of the random distribution of microspheres within a patterned substrate as a reasonable interpretation of the instant claim wording as stated in the above rejection under 35 U.S.C. § 112, second paragraph.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform the Ekins et al. assays with labeled microspheres in patterned microtitre plates with random microsphere distributions within each well thus resulting in the practice of the instant invention.

Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should

be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 23, 2001

ARDIN H. MARSCHEL
PRIMARY EXAMINER